

EXHIBIT 1



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VIA ECF

Hon. Jose L. Linares
United States District Court
Martin Luther King Building & U.S. Courthouse
50 Walnut Street Room 4015
Newark, NJ 07101

Re: United States *ex rel.* Simpson v. Bayer Corporation et al.
Civil Action No.: 05-3895 (JLL)

Dear Judge Linares:

As the Court is aware, on February 19, 2010, the United States declined to intervene in this qui tam matter. Relator has since prosecuted the case on behalf of the United States which remains the real party in interest. *See generally, United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009). On May 20, 2013, pursuant to agreement and court order, plaintiffs and defendants simultaneously submitted their briefing on the pending motion to dismiss in this matter. On May 21, 2013, the Court issued an order setting June 17, 2013, as the motion date for the pending motion to dismiss and indicated that the motion was to be decided on the papers.

After having reviewed the briefing on the pending motion to dismiss, the United States became aware of certain arguments which raise issues of unique concern with respect to the interpretation and application of federal law. The United States thus respectfully requests that the Court accept the attached Statement of Interest for the purpose of clarifying the United States' position with respect to three issues: 1) the circumstances under which the marketing of prescription drugs or violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, may give rise to an actionable claim under the False Claims Act ("FCA"), 31 U.S.C. § 3729; 2) reimbursement under a Diagnosis Related Group (DRG) does not preclude liability under the FCA; and 3) the proper standard for assessing the sufficiency of Simpson's misbranding and AKS claims under Fed. R. Civ. P. 9(b).

Very truly yours,

PAUL J. FISHMAN
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cc - counsel of record by ECF
Atch.